UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,892	12/21/2000	Jack Gauldie	GDI-2	8232

29847 7590 12/06/2002

VAN DYKE & ASSOCIATES, P.A.
7200 LAKE ELLENOR DRIVE, SUITE 252
ORLANDO, FL 32809

EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/06/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,892	Applicant(s) Gauldie
	Examiner Richard Schnizer	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 23, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Jan 22, 2000* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

An amendment was received and entered as Paper No. 12 on 9/28/02. Applicant's election without traverse of Group 1, claims 1-24, drawn to methods and compositions for treating and preventing a disease caused by *P.acnes*, is acknowledged.

Compliance with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s). This application clearly fails to comply with the requirements of 37 C.F.R.1.821-1.825. Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). **Nucleic acid sequences in excess of 10 bases are disclosed at page 19, lines 25 and 29 of the specification, but these sequences are not identified by a SEQ ID NO.**

Applicant must provide:

An initial computer readable form (CRF) copy of the "Sequence Listing".

An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph because the specification fails to enable the full scope of the claimed invention. The specification is enabling for vaccines and vaccination methods known in the prior art and reading on the instant claims e.g. those

disclosed in US Patent 4,057,627 which teaches treatment of acne by oral delivery of inactivated P.acnes bacteria. The specification is also enabled for nucleic acid vaccines comprising a P.acnes lipase gene operably linked to a eukaryotic expression control sequence, and for methods of delivering these vaccines to a rodent by intramuscular, subcutaneous, transcutaneous, intraperitoneal, and intravenous administration for the purpose of limiting the size of skin abscesses caused by P.acnes infection. The specification does not reasonably provide enablement for nucleic acid vaccines which do not express P.acnes lipase, the use of nucleic acid vaccines to completely prevent abscesses, routes of nucleic acid vaccine administration other than intramuscular, subcutaneous, transcutaneous, intraperitoneal, and intravenous, or for methods of treating or preventing acne in any organism other than a rodent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Nature of the invention

The invention is drawn to vaccines for P.acnes and methods of using the vaccines.

Breadth of the claims

Claims 1-10 and 19-23 embrace vaccines comprising a nucleic acid vector encoding any antigen derived from P.acnes, wherein the antigen is capable of generating an immune response in any vaccine recipient. Claims 11-18 embrace methods of treating or preventing a disease caused by P.acnes in any organism. Claim 24 is a method of cosmetically improving the appearance of a

person suffering from acne vulgaris by administering to the person a vector comprising a nucleotide sequence encoding any P.acnes antigen.

Working examples and guidance in the specification

The specification teaches a single working example of the claimed invention. Mice were vaccinated by intramuscular injection of an adenoviral vector encoding P.acnes lipase, or a control adenoviral vector, and then challenged with P.acnes one week after vaccination. The experimental group showed a decrease in abscess size relative to the control group. No evidence was presented indicating that abscess formation could be totally prevented, and no evidence was presented indicating that vaccination could be used to treat pre-existing acne. The specification teaches no working example with any antigen other than lipase. The specification provides no guidance as to which P.acnes antigens would be expected to provide the greatest protection, nor how to use any of the claimed compositions or methods to completely prevent acne, as required by the claims. The specification provides no working example in any organism other than a mouse.

State of the prior art.

The prior art taught the use of acne compositions comprising P.acnes bacteria and P.acnes bacterial derivatives as acne vaccines. See US Patent 4,057,627 to Stickl, which discloses the use of inactivated P.acnes as an oral vaccine for acne vulgaris. See e.g. claims 1-26, and column 8, lines 35-54. See also the discussion at column 1, line 65 to column 2 line 13 which serves as a short review of the use of P.acnes as a vaccine. Note that Stickl refers to "Corynebacterium

acnes", rather than P.acnes. The designation "Corynebacterium acnes" was changed to P.acnes after the publication of Stickl, so one of skill in the art appreciates that Corynebacterium acnes and P.acnes are the same organism. See e.g. Taverne et al (Infection and Immunity 37(3):927-934 (9/1982) abstract). The Stickl disclosure enables instant claims 1-3, 7, 10-12, 15, 16, 20, and 24 because inactivated P.acnes is considered to be a vector comprising nucleic acids encoding all P.acnes antigens. Although the instant specification focuses on nucleic acid vaccines, the claims are sufficiently broad to embrace conventional vaccines, such as inactivated P.acnes bacteria, that incidentally comprise nucleic acids encoding P.acnes antigens. Stickl is not considered to be enabling for a nucleic acid vaccine which must function to produce an encoded antigen by transfection of a host cell.

The state of the art of genetic immunization was set forth by McCluskie et al (Molecular Medicine 5(5): 287-300, 1999). McCluskie considers the effects of the routes of administration of DNA vaccines on the quality of any resulting immune response, and considers the relevance of animal models to practice in humans. Pertinent to the instant case, McCluskie teaches that "promising results in animal models have not been realized in human trials and considerable effort is now being focused at understanding this difference and developing ways of improving the efficacy of DNA vaccines." See final sentence of first paragraph on page 288, column 1. McCluskie points out that "[t]he strength and nature of immune responses in mice with DNA vaccines appear to be influenced by a number of factors [citation omitted]; however, these variables may not be of similar importance in larger animals including humans. As such,

optimization methods developed in mice may not necessarily be applicable to humans." See page 288, column 2, first full paragraph. In fact, it is clear that some vaccines developed in mice do not function at all in some primates. At page 296, column 2, second full paragraph, McCluskie states that "[t]he realization that results in mice often do not predict the situation in humans also led to a large number of DNA vaccine studies in non-human primates, including Aotus monkeys, rhesus monkeys, and chimpanzees. IM injection of plasmid DNA vaccines, while highly immunogenic in mice was found to be only relatively so in chimpanzees and essentially not at all in Aotus monkeys. Furthermore, although early human studies have demonstrated the safety and potential of DNA vaccines, results obtained have not been as good as predicted from animal models. Collectively, these results indicate that no animal model may be ideal for prediction of efficacy in humans [citations omitted]." McCluskie concludes that "[it] is difficult to predict from mouse studies the potential of a new vaccine in humans. In fact, in those human trials that have been carried out, none of the DNA vaccines induced the strong immune responses that had been seen in mice with the same vectors. Furthermore, although non-human primate models are frequently used for development and testing of human vaccines, it is not clear how predictive they will be in the case of DNA vaccines where efficacy, by virtue of the requirement to first transfect cells and express antigens, relies on many factors other than immunological responses to the antigen. We will not know the answer to this until after greater experience has been achieved in non-human primates and human clinical trials." Thus the success in primates of vaccines developed in mice is considered by those of skill in the art to be unpredictable.

Regarding the route of administration of the vaccine, McCluskie taught that this variable "influences the strength and nature of immune responses in mice and non-human primates. However, the results in mice were not always predictive of those in monkeys and this is likely true for humans as well. Optimal dose and immunization schedule will most likely vary between species. It is not clear whether results in non-human primates will be predictive of results in humans, thus additional studies are required." McCluskie tested eight injection-mediated routes including intravenous, intramuscular, subcutaneous, and intraperitoneal, six non-injection routes including the claimed oral, ocular, inhalation, and intrarectal routes, and one transcutaneous route (gene gun). The results indicated that whereas substantial immune responses were obtained by IM, IV, sublingual, and intradermal injection, as well as by gene gun, none of the non-injection routes gave rise to any antibodies. See abstract, and Fig. 1 on page 291. This is objective evidence that the route of DNA delivery influences the immune response obtained in genetic immunization, and that the results obtained by oral, ocular, inhalation, and intrarectal routes are unpredictable.

Regarding the relevance to human disease of the acne mouse model disclosed in the specification, a search of the prior art indicated that the mouse has not been established as an accepted animal model of acne. No citations were discovered in which a mouse was used to study acne lesions such as those described in the instant specification. It is noted that De Young et al (J. Inv. Derm. (83(5): 394-398, 11/1984) developed a rat model for acne by injection of P.acnes into the ear of the animal. However, Whyte et al (J. Comp. Pathol. 122 (2-3): 17-184,

4/2000) taught that while some animal models mimic certain aspects of acne, few represent the chronic nature of the response seen in the human. Whyte notes that the system of De Young was limited because only histological assessments were made and only a few sites per animal could be tested (page 177, column 2, lines 3-12). Whyte further notes that rodent skin is dissimilar to human skin in terms of its histology, chemical composition, permeability, and arrangement of hair follicles and pilosebaceous glands, and for these reasons the pig is a superior model (page 178, lines 14-19).

Predictability of the invention

One of ordinary skill in the art appreciates that, in order to function as a useful antigen for microbial vaccine purposes, a target antigen must be one that is expressed on the surface of the microbe so that intact, live microbes may be recognized by the immune apparatus. For this reason, the scope of the claims embracing P.acnes antigens that are not expressed on the cell surface would not be considered to be enabled by one of skill in the art. The specification discloses three antigens that are expressed on the surface of P.acnes, lipase, hyaluronidase, and an unnamed phosphatase. It is noted the genus of phosphatase must include intracellular and extracellular phosphatases, and all microorganisms comprise intracellular phosphatases. Examples include hexokinase and phosphoglycerate kinase, glycolytic enzymes that transfer a phosphate from ATP to glycolytic substrates. These enzymes, because they hydrolyze phosphate esters, can be considered to be ATP phosphatases. Because glycolytic enzymes are located on the interior of the cell, they cannot function as vaccine antigens.

In further consideration of the scope of the invention embracing phosphatases as antigens, the prior art indicates that P.acnes exocellular phosphatase is not antigenic in mammals. Ingham et al (Br. J. Derm 116(6):805-812, 6/1987) teach that no antibodies to exocellular phosphatase could be detected in humans with acne regardless of the severity of the disease. See abstract. Additionally, Ingham (Br. J. Derm 110(1):61-66, 1/1984) taught that antibodies to P.acnes exocellular phosphatase could not be raised in rabbits. See abstract. Furthermore, each of these references indicates that P.acnes hyaluronidase was substantially less antigenic than lipase. Ingham (1987) teaches that hyaluronidase antibodies were found only in adult humans, and that these adults were far more likely to have lipase antibodies than hyaluronidase antibodies. Ingham (1984) showed that antibodies to hyaluronidase could not be raised in rabbits by injection of the purified antigen, rather *in vitro* incubation of mononuclear cells in antigen was required for induction of an immune response. See abstract. These data demonstrate the unpredictability of raising a preventive, or even protective, immune response to P.acnes exocellular phosphatase and hyaluronidase specifically, and call into question the predictability of raising protective or preventive immune responses against P.acnes antigens in general.

Regarding the treatment of existing conditions by genetic immunization, Irvine et al (J. Immunol. 156(1): 238-245, 1996) teach that "DNA immunization alone had little or no impact on the growth of established lung metastases", and Lewis et al (Adv. Vir. Res. 54:128-188, 1999) note a case in which genetic immunization resulted in exacerbation of disease progression (see page 169, column 2, lines 1-3 of second paragraph). Furthermore, as noted in the specification

and specific to the claimed invention, Karvonen et al (Dermatology 189:344-349, 1994) and Holland et al (Exp. Dermatol. 2:12-16, 1993) teach that immune responses to some P.acnes antigens can actually contribute to the disease process.

In summary, the state of the art of genetic immunization suggests that it is generally unpredictable which antigens will provide a protective or preventive immune response, the prior art teaches that immune responses to some P.acnes antigens actually contribute to the disease process, and that some P.acnes antigens are poorly or undetectably antigenic in mammals. Also, the significance of results in the disclosed animal model are unknown because it is not a recognized animal model of human acne, and because the prior art teaches that genetic immunization of mice may not be predictive of results in primates. The specification fails to teach which P.acnes antigens, other than lipase, will provide a protective immune response, and fails to teach how to use any P.acnes antigen to totally prevent any disease associated with P.acnes. The specification fails to provide any technical guidance that would improve the state of the art of genetic immunization in general, and therefore does not reduce the unpredictability associated with genetic immunization in general, or with P.acnes immunization specifically. Given the state of the art, the unpredictability of the art, the level of exemplification, and the teachings in the specification, one of skill in the art would have to perform undue experimentation in order to practice the invention commensurate in scope with the claims.

Written Description

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above, the claimed invention is drawn to nucleic acid vaccines encoding any P.acnes vaccine that can be used to treat or prevent a disease caused by P.acnes. Claims 1-9 and 11-24 embrace any P.acnes antigen that can cause an immune response in a recipient. Claim 10 is limited to the genus of antigens encoded by any P.acnes lipase, hyaluronidase, or phosphatase gene.

The following analysis is based on the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage on the treatment of genus claims is particularly relevant.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within a genus, one must describe a sufficient number of species to reflect the variation within the genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

The specification teaches how to isolate lipase genes by PCR but fails to identify by complete structure any nucleic acid encoding any antigenic P.acnes polypeptide. The specification discloses no relevant structural characteristics such as correlation between nucleic acid or polypeptide structure and the antigenic function required by the claims. The scope of even the narrowest claim, claim 10, embraces numerous naturally occurring structural variant, including allelic variants. The claimed genus is highly variant because the only structural requirement is the encoded proteins must be antigenic in a host. However, as noted above under enablement, it is not clear which P.acnes proteins are antigenic and which are not, and the specification provides no guidance in this matter. The specification teaches no structural features that could distinguish the compounds of the claimed genus from other antigenic proteins, and no common structural attributes identify the members of the claimed genus.

The courts have found that merely describing the functional characteristics of a protein encoded by a particular nucleic acid is insufficient to adequately describe the genus of nucleic acids encoding that protein. A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. See Oka, 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., antigenicity, because an alleged

conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. When an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The instant application does not provide a written description that would allow one of skill in the art to immediately envisage the specific structure for the genus of antigenic polypeptides and polypeptide fragments. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). As there is no disclosure of the polynucleotides, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The failure to disclose any member of the genus by complete structure, or to disclose appropriate identifying characteristics of the species of the claimed genus, combined with the breadth and the variability of the claimed nucleic acids, results in a finding that one of skill in the art could not conclude that Applicant was in possession of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because it recites "said P.acnes" without antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 10-12, 15, 16, 20, 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stickl (US Patent 4,057,627, 11/8/1977), as evidenced by Taverne et al (Infection and Immunity 37(3):927-934 (9/1982)).

Stickl teaches compositions comprising inactivated P.acnes and their use as oral vaccines for acne vulgaris. See e.g. claims 1-26, and column 8, lines 35-54. Note that Stickl refers to "Corynebacterium acnes", rather than P.acnes. The designation "Corynebacterium acnes" was changed to P.acnes after the publication of Stickl, so one of skill in the art appreciates that Corynebacterium acnes and P.acnes are the same organism. See e.g. Taverne et al (Infection and Immunity 37(3):927-934 (9/1982) abstract). The Stickl disclosure anticipates instant the claims because inactivated P.acnes is considered to be a vector comprising nucleic acids encoding all P.acnes antigens. Because the nucleic acid encodes all P.acnes antigens, the vaccine can be considered to comprise a nucleic acid encoding an adjuvant, as required by claims 7 and 22. Stickl also teaches that the vaccine may be disposed within a bottle as required by instant claim 20. See column 6, lines 44-52. The vaccine may be aqueous as required by instant claim 21. See abstract.

Summary

All claims lack adequate written description and enablement.

Claim 24 is indefinite.

Claims 4-6, 8, 9, 13, 14, 17-19, and 23 are free of the art of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

JEFFREY SIEW
PRIMARY EXAMINER
11/27/02